REMARKS

At the outset, the Examiner is thanked for the thorough review and consideration of the pending application. The Final Office Action dated June 27, 2008, has been received and its contents carefully reviewed.

Claims 8, 25, 30-34, 40, and 42 are hereby amended. Claims 36-39 and 43 are hereby canceled without prejudice or disclaimer. Claim 51 is hereby added. No new matter has been added. Accordingly, claims 1-35, 40, 42, and 44-51 are currently pending. Reexamination and reconsideration of the pending claims are respectfully requested.

The Office Action objects to claims 36-39 and 42-43 because of informalities. Specifically, the Office Action alleges the claims 36-39 are duplicates of claim 35 and claim 43 is a duplicate of claim 42. Not necessarily agreeing with the Examiner, Applicant has canceled claims 36-39 and 43.

The Office Action rejects claims 27-34, 38-40, 43, and 45-46 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Claims 38-39 and 43 are canceled, so the rejection of these claims is moot. Applicant respectfully traverses the rejection of claims 27-34, 40, and 45-46.

"To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997). The factors to be considered in determining whether it would take undue experimentation to obtain an invention include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

predictability or unpredictability of the art, and (8) the breadth of the claims." *In re wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Claims 27-34, 40, and 45-46 relate to the treatment of diseases, the method for preparing the medicament, and the composition for use treatment of diseases. Applicant submits that the specification sufficiently support this subject matter. The specification provides "[t]he ***medicaments*** containing the ***compound (or compounds) (I)*** alone can be administered at doses which can be determined beforehand by means of ***routine experiments***, according in particular to the desired effect[, and t]hese doses may range, for example, from 0.1 to 200 mg per individual and per day, preferably from 1 to 50 mg." *Specification*, page 20 line 33, to page 21, line 3, emphases added. *See also Specification*, page 2, lines 10-32. The Specification further provides "[i]t should be recalled, in this respect, that gamma-interferon is a pro-inflammatory cytokine, the presence of which characterizes a certain number of pathologies associated with inflammation. In such situations, it is useful to suppress or reduce the biological activity of the endogenous gamma-interferon. In animals, experimental models have proved the advantage of such a strategy (inhibition of gamma-interferon) by using inhibitory monoclonal antibodies or soluble form of the cytokine receptor. By way of example, mention may be made of autoimmune or degenerative diseases (multiple sclerosis, glomerulonesphritis, Crohn's disease, rheumatoid arthritis, etc.). Similarly, the inhibition of gamma-interferon may be an effective supplement to immunosuppressive treatments, for example, with cyclosporine that are used, for example, to prevent transplant rejection." *Specification*, page 20, lines 15-31.

The Office Action states that "[n]o arguments have been advanced as to why the methods of treatment as instantly claimed are enable." Applicant respectfully disagrees. The above recited specification clearly satisfies the enablement requirement. Moreover, methods of treatment with known medicaments are well-known in the art. Therefore, no undue

experimentation would be necessary for one of ordinary skill in the art to practice the inventions of claims 27-34, 40, and 45-46 and replace the known medicaments with the compound according to claim 1. Applicants, therefore, respectfully requests withdrawal of the rejection of claims 27-34, 40, and 45-46.

The Office Action rejects claims 8, 30-31 and 39-40 under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Examiner states the phrase "for example" renders the claims 8, 30-31, and 39-40 indefinite. Applicant respectfully disagrees. However, claim 39 is canceled, so the rejection of claim 39 is moot. Applicant has also amended claims 8, 30, 31, and 40 and added new dependent claim 51. Claims 8, 30, 31, and 40 more clearly define the claimed subject matter. Applicant respectfully requests withdrawal of the 35 U.S.C. § 112, second paragraph, rejection of claims 8, 30-31 and 39-40.

The Office Action rejects claims 25, 32-34, and 42-43 under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 43 is canceled, so the rejection of claim 43 is moot. Not necessarily agreeing with the Office Action, Applicant has amended claims 25, 32-34, and 42 to more clearly define subject matter. Applicant, therefore, respectfully requests withdrawal of the 35 U.S.C. § 112, second paragraph, rejection of claims 25, 32-34, and 42-43.

The Office Action rejects claims 1-17, 24-40, and 42-50 under 35 U.S.C. § 103(a) as being unpatentable over PCT Application Publication No. WO 97/03700 to Lortat-Jacob (*Lortat-Jacob*) in view of Cytokine, 8(7): 557-566 (1996) (*Cytokine*) and PCT Application Publication No. WO 93/19096 to Turnbull et al. (*Turnbull*). Claim 36-39, and 43 are canceled, so the rejection of these claims is moot. Applicants respectfully traverse the rejection of claims 1-17, 24-35, 40, 42, and 44-50.

To establish *prima facie* obviousness of a claimed invention, all the claim elements must be taught or suggested by the prior art. The combined teaching of *Lortat-Jacob*, *Cytokine*, and

Turnbull fails to teach or suggest all the elements of claims 1-17, 24-35, 40, 42, and 44-50, and thus, can not render these claims obvious.

Independent claim 1 recites, *inter alia*, "molecules corresponding to formula (I)." Formula (I) has two oligosaccharide fragments A and B, which are placed on either side of the spacer group X and have an arrangement that can be described as symmetrical with respect to the spacer group X. *Lortat-Jacob* fails to teach at least this feature of claim 1. In fact, the Office Action admits that "Lortat-Jacob et al do not exemplify a compound of instant formula (I) ... wherein the saccharide units on either side of the spacer group are symmetrical." *Office Action dated September 19, 2007*, page 9, lines 12-15. The Office Action, however, alleges that "[t]he fact that [groups A and B in *Lortat-Jacob*] may be similar is a suggestion that the compounds of instant formula can be symmetrical (by being the same)." *Office Action dated June 27, 2008*, page 6. Applicant respectfully disagrees. The Examiner fails to recognize the distinction between "similar" and "symmetrical." Being similar does not equate to being symmetrical. As discussed in the specification, "the molecule according to the invention has specific structure due, first of all, to the fact that the two oligosaccharide groups, placed on either side of the spacer group X, have an arrangement that can be described as 'symmetrical' or 'antiparallel' with respect to the spacer arm, whereas, both in natural heparin and heparin sulphate molecules and in synthetic heparins, and in the similar molecules described in the prior art, the two oligosaccharide groups have a 'parallel' or 'asymmetrical' arrangement. These molecules do not therefore observe the symmetry of the protein to which they are capable of binding. In other words, the natural molecules and the molecules of the prior art, whether this involves heparin, heparin sulphate or molecules similar thereto, are completely an entirely asymmetrical, i.e., they are in a form of '1212' type, whereas the molecules of the invention are in antiparallel form of type '1221', i.e., having a C2 type symmetry." *Specification*, page 8, line 23, page 9, line 14. In

Lortat-Jacob, there is no indication of the geometry of the molecules. To the contrary, *Lortat-Jacob* discloses similar molecules, which, as discussed in specification of the present application and repeated above, are likely to have the conventional "parallel" or "asymmetrical" arrangement instead of the "symmetrical" or "antiparallel" arrangement of formula (I) of claim 1. Additionally, to the extent the Examiner is making an inherency argument, it is respectfully submitted that "can be" does not meet the standard of "necessarily present." *See M.P.E.P.* 2112(IV). Accordingly, it is improper to conclude that *Lortat-Jacob* inherently teaches symmetrical arrangement simply because similar groups "can be" symmetrical. *Lortat-Jacob*, therefore, fails to teach or suggest the above identified features of claim 1.

Claim 1 also recites "an SO_3^- group or a phosphate group, with the proviso that no SO_3^- group is in the 3-position of the glucosamine units of compound (I)." *Lortat-Jacob* also fails to teach or suggest at least this feature of claim 1. By precluding sulphate groups at the 3-position, formula (I) avoids the anticoagulant drawbacks associated with the prior art. *See* e.g., *Specification*, page 9, lines 16-29. *Lortat-Jacob* altogether fails to recognize this property and thus the very purpose of avoiding a sulphate group at the 3-position of the glucosamine unit as claimed. In fact, *Lortat-Jacob* actually teaches adding anionic groupings (sulphate, phosphate) in a sufficient quantity on the biocompatible polymers. *See Lortat-Jacob*, page 11, lines 16-18. Accordingly, *Lortat-Jacob* also cannot teach or suggest this additional feature of claim 1.

Cytokine and *Turnbull* fail to cure the deficiencies in *Lortat-Jacob*. *Cytokine* is only cited by the Examiner for disclosing γ-interferon and the role of heparan sulfate. Importantly, *Cytokine* also fails to teach or suggest the above-recited features of claim 1. *Turnbull* also fails to cure the deficiency in *Lortat-Jacob*. The Office Action states "Turnbull et al ... teaches that herapin or herapan sulfate with the complexity and heterogeneity with a large number of different disaccharide units may have different activities and have undesired side effects and

would lack specificity in binding to growth factors on cell surfaces" and concludes that "[t]his means that the structure of the saccharide units in heparin or heparan sulfate should be same or uniform for reducing the side effects and increasing the beneficial activity." *Office Action dated September 19, 2007*, page 10, lines 5-11. This analysis is fundamentally flawed. *Turnbull* only appears to describe the composition containing the compound and not the actual structure of the compound. Therefore, the language regarding uniformity likely relates to the composition instead of the structure. Even if it did relate to the structure of the compound, the recitation in *Turnbull* still fails to teach or suggest the elements of claim 1. The Examiner again appears to confuse "same" or "uniform" with "symmetrical." As explained above with respect to *Lortat-Jacob*, that the structure of the saccharide units are the same or uniform does not necessarily mean that they are also symmetrical. *Turnbull*, therefore, simply does not provide any teaching or suggestion to make fragments A and B uniform, let alone symmetrical as erroneously concluded by the Examiner. As such, *Turnbull* cannot cure the deficiencies of *Lortat-Jacob* and *Cytokine*.

Accordingly, claim 1 is patentable over the combined teaching of *Lortat-Jacob*, *Cytokine*, and *Turnbull*. Claims 2-17, 24-35, 40, 42, and 44-50 and newly added claim 51, variously depend from claim 1 and are, therefore, also patentable over the combined teaching of *Lortat-Jacob*, *Cytokine*, and *Turnbull* for at least the same reasons as claim 1. Thus, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of claims 1-17, 24-40, and 42-50.

The application is in condition for allowance. Early and favorable action is respectfully solicited. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at (202) 496-7500 to

discuss the steps necessary for placing the application in condition for allowance. All correspondence should continue to be sent to the below-listed address.

If these papers are not considered timely filed by the Patent and Trademark Office, then a petition is hereby made under 37 C.F.R. § 1.136, and any additional fees required under 37 C.F.R. § 1.136 for any necessary extension of time, or any other fees required to complete the filing of this response, may be charged to Deposit Account No. 50-0911. Please credit any overpayment to deposit Account No. 50-0911. A duplicate copy of this sheet is enclosed.

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Respectfully submitted,

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